EXHIBIT 267

Healthcare Compliance Guidelines

September 2004

NOVARTIS

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It is the goal of Novartis Pharmaceuticals Corporation to ensure that its marketing and promotional activities comply with all applicable state and federal laws. All employees are expected to know and adhere to these guidelines.

Novartis policies and the PhRMA Code on Interactions with Healthcare Professionals exist to help Novartis and its employees adhere to the law. Your review and understanding of The Federal Fraud and Abuse Statute and The False Claims Act is therefore essential as these laws apply to all of the types of activity discussed within the Healthcare Compliance Guidelines (e.g., Grants, Speaker Programs, Scientific Operations, Gifts, Consulting, etc.), as well as to other activities that may not be specifically addressed in these guidelines.

The Federal Fraud and Abuse Statute

The Medicare and Medicaid Antikickback Statute makes it illegal to knowingly and willfully provide any "remuneration" in return for:

(1) referring a person to another person for items or services covered under federal health care programs; or

(2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.

"Remuneration" is defined very broadly and includes any item of value which is provided with the *intent to induce* the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program – not just Medicare and Medicaid (CHAMPUS, VA benefits, etc.). Note again that many state statutes similarly prohibit such activities.

Under the Antikickback Statute, it is illegal to *solicit* (ask for) or *receive* kickbacks, as well as to *offer* to pay a kickback. Any of these actions constitutes a felony and is punishable by a fine up to $25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity's right to provide products and services to patients whose care is paid for by government programs.

Judicial and administrative interpretations of this law have been very broad. For example, the Office of Inspector General (OIG) of the Department of Health and Human Services, which is responsible for the civil and administrative enforcement of the Antikickback Statute, has made it clear through several "fraud alerts" and in the recently issued Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers that the following practices will be considered violations of the statute:

Practices violating the statute

- "Research grant" programs in which physicians are given substantial payments for minimal record keeping tasks, or which are of questionable scientific value.
- Payment of a physician's travel and expenses to attend conferences.
- Payment for a physician's CME courses.
- Provision of valuable free or discounted items or services to the physician (such as computers, fax machines, frequent flyer miles or vacations).

Most importantly, actual enforcement cases have established several interpretive principles that will apply to any case being reviewed under the statute. These include the following:

Interpretive Principles

- The statute is violated if even *one purpose* (as opposed to a primary or sole purpose) of a payment is to induce the referral of patients or the ordering, purchasing, or recommending of items or services.

- A payment or other benefit violates the statute whenever the manufacturer's intent is to induce the Healthcare Professional to prescribe its product.

  The government will infer that such intent is present when the amount is *large or frequent* and is seemingly not justified by the supposed purpose of the payment (e.g., a free trip, a grant for "research" that lacks substance, an honorarium for consulting which lacks substance, or an honorarium which is greater than fair market value). Some benefits, however, such as drug samples (which are regulated by a separate statute), pens, or notepads, are likely to be construed as too insignificant to affect referral practices.

- There need be *no proof of an agreement* to make referrals, or to order, purchase or recommend drugs or services, for illegal intent and a violation to be found. Intent may be inferred from the circumstances of the case.

- The fact that a particular *arrangement is common* in the health care industry is *not a defense*.

  Although the Code of Federal Regulations contains several "safe harbors" under the statute, such as personal services agreements (e.g., physician consulting agreements) which comply with the statute's criteria, most marketing and promotional practices will not fall clearly or completely within the parameters of these "safe harbors" but must instead be analyzed on a case-by-case basis. In such an environment, it is imperative that all Novartis employees know and adhere to these guidelines, which have been drafted in order to assist Novartis employees in carrying out their work while complying with the law. Typically, far more will be at stake in potential criminal fines and civil penalties than the amount of the grant or promotional expenditure at issue.

The False Claims Act

A separate, but related law governing pharmaceutical sales and marketing practices is The False Claims Act. Filing or facilitating the filing of "false claims" against the Government is a violation of this law and can lead to huge fines and penalties. Claims submitted for reimbursement from Federal health care programs tainted by any number of problems, including prescriptions written where a kickback has been found to be present, are alleged by the Government to be "false claims." In addition to triggering the huge fines, The False Claims Act contains a whistleblower provision. Whistleblowers who meet the requirements set forth in this law, and who successfully establish the existence of "false claims," are entitled to share in the proceeds of any judgment or settlement. Some recent high visibility whistleblower suits against pharmaceutical companies have resulted in whistleblower payments in the tens of millions of dollars.

Novartis Pharmaceutical Corporation provides policy guidance and notice of relevant regulatory requirements with the expectation that all employees know and adhere to them. We ask that any person with information about activities that may be fraudulent contact the AlertLine at 1-800-543-6502 so that management can take any and all steps necessary to immediately address the situation.

The FDA and Pharmaceutical Promotion

The Food and Drug Administration, and in particular, the Division of Drug Marketing Advertising and Communications (DDMAC), is empowered by law to regulate pharmaceutical promotional activity. Our promotional and related activities must meet the highest standards of scientific rigor and objectivity and must, in accordance with applicable regulations, present a balanced discussion of our products.

Additionally, recent media coverage has been intense and negative. Thus, there is even more reason to ensure that all of our marketing and sales activities live up to the high standards that are expected. This section will discuss the basic requirements as well as Novartis policies designed to ensure our compliance.

Key Requirements of Novartis Promotional Materials and Programs

Consistency with Approved Labeling

- A promotional claim is any characterization of our product beyond its name, available dosage strengths and price.
- All promotion of Novartis products must be consistent with approved package inserts (i.e., approved labeling) as well as any specific directives made by the FDA.
- Every promotional communication must be cleared by a designated "Core Team" consisting of Marketing, Medical, Regulatory and Legal experts for that product.
- Generally, our promotional materials should mention the explicit indication being promoted. This can be supported by data on the primary efficacy endpoints from the pivotal trials.
- Secondary endpoint data should be used only if the primary endpoint data is disclosed.
- Claims based on studies where the studies are not in our label can only be disclosed if the claims are consistent with our label or if they meet the standard of "substantial evidence" – usually defined to be two adequate and well-controlled trials.
- Head-to-head package insert comparisons are not acceptable for making promotional claims.
- Claims established by other similar products cannot be made about our product in the absence of clinical trials of high scientific caliber showing that benefit for our product.
- Clinical claims cannot be made from animal data, open-label trials, retrospective analyses, post hoc sub-group analyses or similar selective interpretations falling short of the FDA's standard of "substantial evidence".

Fair Balance

- All promotional pieces and discussions must include appropriate fair balance – a presentation of the major risks and common side effects that patients may encounter.
- Fair balance regarding efficacy must be presented at least once in the piece or discussion; fair balance for safety must be presented on every spread or time during discussion when a safety claim is made.
- Providing the full package insert is generally not sufficient to meet the fair balance requirement.
- Disclaimers may be necessary to provide the reader with appropriate perspective regarding a promotional claim. However, it is not appropriate to use a disclaimer to temper an exaggerated claim.

Guidance for Marketing & Related Personnel

- Fair balance must be presented with reasonably comparable prominence and detail to the major claims being made for the product.
    - Typically, reasonably comparable prominence has been defined as no less than one point size smaller text. However, the assessment is, by its nature, qualitative.
- Fair balance cannot be relegated to the back of the piece, but must be interspersed with the main messages of the piece.

Disclosure

- Full prescribing information must be left with Healthcare Professionals whenever we communicate promotional information about a Novartis product.
- Generally, promotional pieces should direct readers to the full prescribing information if promotional claims are being made in that piece. The direction to refer to full prescribing information should be made on every spread.

Guidance for Marketing & Related Personnel

Post-FDA Approval Promotion

With the exception of reminder ads for non-black box products, all promotional pieces mentioning a Novartis product require the following:

1. Product or "proprietary" name;
2. Generic or "established" name, which needs to be in typeface at least half as large as that for the product name and used at least once per spread with the most prominent mention of the product name;
3. Quantity of each active ingredient;
4. At least one specific dosage form;
5. Fair Balance (see above);
6. At least one indication; and
7. Directions to consult the accompanying full Prescribing Information (or Brief Summary of Prescribing Information in the case of journal ads) on each spread.

Special Situations

Black Box Products – Leave Items

- The PI must accompany all leave items associated with black box products. In these situations, it is preferable to make written reference to the accompanying PI on the leave item itself so that our intent is clear after the item is opened and the PI is removed.
- The fair balance information must also be included if the leave item suggests an indication.

Promotional Stickers

- Novartis allows the use of Core Team approved stickers on promotional materials and sample cartons (trays or packer boxes), but not on individual sample boxes or packages (blisters, bottles, etc.), and not on prescription pads.
- All stickers should be printed on transparent stock and should not obscure any existing wording on sample cartons or promotional materials.
- Promotional stickers can be used on pizza/doughnut boxes, and other foods.
- Promotional stickers are not to be used on gifts or textbooks.

Program Invitations

- All invitations to Novartis promotional programs require review and approval by the respective product Core Team.

Marketing Research of Promotional Materials

In some circumstances, a Brand team may want to test visual aids with sales associates prior to full-scale roll-out.

- If the visual aid will only be viewed by the field sales associate for testing purposes and in the process will not be shown to a Healthcare Professional, then Core Team approval only is required before testing.
- If an item is disseminated to a field sales associate for use with a Healthcare Professional, it is considered promotion and must be:
  1. Core Team approved, and
  2. filed with DDMAC at first use.

Sales Associates are not to ask or discuss marketing research questions of their doctors.

Promotion – "In-Label" and "Off-Label" Considerations

- FDA regulations specify that "A drug … shall be deemed to be misbranded if its labeling is false or misleading in any particular."
- Promotional or "In-Label" Reprints: Reprints that are fully consistent with approved labeling, and approved by Core Team, are acceptable for promotional use.
  - Reprints approved for promotion may be shown to, left with, and discussed with Healthcare Professionals.
- "Off-Label" Reprints: Reprints that are not consistent with approved labeling. Such reprints can not be used for promotion.
  - Off-label reprints can be sent to doctors by Medical Affairs personnel if:
    - the doctor makes an unsolicited request for information, and
    - the off-label reprint directly bears on the question the doctor is asking
  - In rare circumstances, a Core Team may consider allowing off-label reprints to be disseminated by the Field when:
    - very high doctor demand for information
    - study of the highest scientific caliber
    - off-label elements do not represent significant patient risk
    - dissemination is not part of a larger campaign to promote off-label use
    - explicitly approved by the Core Team Oversight Committee (CTOC)
  - Brand will instruct the Field via Tactical Memo as to appropriate use.
    Note: Dissemination does not allow Representatives to detail from an off-label reprint

- Brand Teams may not provide off-label reprints, articles, or any other non-Core Team approved material in response to a request from a field representative(s). All such material must be Core Team approved before distribution.
- Field representatives may not participate in recruiting activities for clinical trials as this is off-label activity.

Use of Unapproved Promotional Materials ("Homemade Bread")

- Promotion includes any material provided to potential users or decision-makers regarding our products that makes a claim about a Novartis product.

  It also includes verbal statements made by representatives of our company.
- The use of any material or claims not approved by the Novartis Promotional Review Process in the promotion of our products is strictly prohibited.
    - For example, changing, revising, or using a portion of a Core Team approved promotional piece is considered "Homemade Bread" and is strictly prohibited; To use such material, full Core Team review and approval would be required as it would be considered a new promotional piece and requires DDMAC submission.
- The use of unapproved promotional materials will result in disciplinary action up to and including termination.

Competitor Promotional or Other Material

Photocopying of competitor promotional material for our promotional use is strictly prohibited. In the event competitor promotional or other material is distributed at public events (e.g., conventions, exhibits) and such material is obtained by Novartis personnel, using such material in a promotional manner (e.g., Novartis promotional material, sales representative detailing) is also strictly prohibited.

- As noted elsewhere, in the absence of a Core Team approved promotional comparison against a competitor product, comparisons between Package Inserts are prohibited. That is, no discussions or promotional messages may occur based on comparisons of Package Inserts.

Guidance for Marketing & Related Personnel

Pre-FDA Approval Activities

A company may not represent that an investigational drug is safe or effective. Despite this prohibition, FDA permits the following two options for pre-approval activities:

1. A *"Coming Soon"* product mention where the product name alone is used without any mention of an indication or any written verbal or graphic representation or suggestion concerning the safety, efficacy or intended use.

   "Coming Soon" ads may not be used for pre-FDA approval promotion of drugs that are likely to have a boxed warning ("black box").
2. An *"Institutional Mention"* which states that a drug company is conducting research in a therapeutic area to develop new drugs. The advertisement may not mention any drug name.

Once either option is chosen for pre-approval promotion, it cannot be changed nor can the options be mixed.

Launch Advertising

- Novartis policy requires that major launch materials containing the major claims (e.g., core sales aid, journal advertisement) be submitted to DDMAC prior to use for their comments. Other materials not submitted to DDMAC (e.g., slide kits, monographs) must be modified in a manner consistent with DDMAC comments on the core pieces.
- No changes to the major claims can be made during the launch period (i.e., the first six months) without additional review by DDMAC personnel.
- The "new" designation for a drug can only be used in advertising for the first six months after the launch of the drug.

PI (Package Insert) and PI Derivatives

Novartis contracts with Newark Trade, 973-674-3727 to manage the development of all PIs, both Patient and Healthcare Professional, Brief Summaries, both Patient and Healthcare Professsional, and PI Detail Aids. Newark Trade maintains the database for all the latest labeling information and the layout criteria for PI and Brief Summary documents.

Ad Agencies are not authorized to create, layout or produce PIs, Brief Summaries or PI Detail Aids.

- PI - Brand must direct all requests for PI to Newark Trade by completing a Newark Trade PI Request Form and copying the appropriate Novartis Print Production Specialist.
- Brief Summaries - The Brand Team or their delegate (Ad Agency) must request Brief Summaries through Newark Trade by completing and submitting a Newark Trade PI Request Form to Newark Trade. This request must specify any special requirements such as the inclusion of only one or the latest approved indication. Newark Trade will create the layout of the Brief Summary which will be returned to the Brand Team or their delegate (Ad Agency) so that it can be submitted through the Core Team Review Process. After Core Team Review, any Core Team mandated changes are incorporated by Newark Trade and forwarded back to the Brand Team or their delegate. Brand Team must request the release of the disk for print production through Novartis Print Production.
- PI Detail Aids - Usually during a Launch Pre-clearance phase, while Brand Team is awaiting comments from DDMAC on the use of key promotion pieces for a new product launch or newly approved indication, a PI Detail Aid becomes a necessary promotion tool for field sales reps to detail from.

The following process details the Core Team Review process:

- Core Team must review/approve all PI Detail Aids in their entirety.
- Brand Team or their delegate (Ad Agency) will provide cover layout and template for inside layout of the PI Detail Aid brochure to Newark Trade along with a Newark Trade PI Request Form.
- Newark Trade will create inside layout according to template guidelines provided by Brand Team or their delegate (Ad Agency).
- When completed, Newark Trade will provide complete layout of cover and inside contents to Brand Team or their delegate (Ad Agency) so that it can be submitted through the Core Team Review Process.
- After Core Team Review, any Core Team mandated changes are incorporated by Newark Trade and forwarded back to the Brand Team or their delegate.
- Brand Team must request the release of the disk for print production through Novartis Print Production.

Reminder Ads

- These ads call attention to the name of the product but not its indication or dosage recommendations. A reminder ad does not require Prescribing Information or a Brief Summary.
- The reminder ad must contain:
    - the product (proprietary) name,
    - registered trademark, and
    - the generic (established) name.
- Ads or leave items for Black Box products require that Prescribing Information be provided, therefore, these are not considered reminder ads.
- Promotional pieces suggesting an indication or use of the product graphically or in writing are not reminder ads and must meet the usual requirements of pharmaceutical promotion.

Direct to Consumer Advertising (DTC)

Novartis policy requires that DTC campaigns be submitted to DDMAC prior to use for their comments based on the criteria stated below.

- Whether modifications to an existing DTC campaign warrant such review will be determined by the Brand Core Team.

Policies on Submitting Materials to DDMAC for Comments Prior to Use

Novartis acknowledges the benefits that FDA, as well as Novartis, obtain from receiving comments from DDMAC on certain promotional items prior to their use.

- For any product receiving accelerated review, DDMAC requires that all promotional material be pre-cleared prior to use. All promotional materials intended for dissemination or publication within 120 days following marketing approval must be submitted to DDMAC for comments prior to approval. DDMAC usually provides comments within 15 working days.
- Major physician-oriented promotional materials (e.g., journal ad, sales aid) for a product about to be launched must be submitted to DDMAC for comments.
    - DDMAC's comments must be addressed through revisions deemed appropriate by the product's Core Team prior to using these materials promotionally.
    - Materials not sent down to DDMAC (e.g., spin-offs from the core material, slide kits, mono-graphs, etc.) must be modified to reflect DDMAC feedback on major pieces.
- The above policy may also apply to promotional materials for a new label change deemed "major" by Drug Regulatory Affairs.
    - The introduction of a new dosage strength for Lotrel, and the addition of the Heart Failure indication for Diovan would both be considered "major" changes.
- Submission of materials to DDMAC for comments is also required for initial and major new DTC campaigns on behalf of our products.
    - As with launch materials, DDMAC's comments must be addressed through revisions deemed appropriate by the product's Core Team prior to using these materials promotionally.

- The following items do *not* need to be pre-cleared:
    - Disease state ads with no product claims.
    - Items disseminated via a learned intermediary to patients.

The above requirement regarding DTC communications may be waived by the product's Core Team under certain limited circumstances. These include:

1. Where the campaign will use claims similar to those made in a previously pre-cleared DTC campaign.
2. Where nearly identical material has been used for at least six months in patient information delivered through a learned intermediary. In these instances, Core Team should re-review the materials with a clear understanding of their new purpose and the fact that DDMAC will not be explicitly pre-clearing these materials.
3. Where it is highly likely that DDMAC will decline to review our submission (e.g., where nearly identical claims are already being used in a professional campaign).

In all other cases a waiver of the pre-clearance requirement can only be obtained after a complete review of the issues by CTOC.

All promotional materials for products approved via the accelerated approval process must be pre-cleared in a manner consistent with FDA's rules governing this area.

- DTC ads are any messages, which Novartis directs to patients, bypassing the "learned intermediary."
    - Learned intermediary includes Healthcare Professionals such as Doctor, Nurse, Physician Assistant.
    - Note that professionals hired, or otherwise compensated by Novartis or its agencies to communicate messages to consumers, are not acting as learned intermediaries, but rather as promotional agents for Novartis. Such communications must be treated as Direct to Consumer Advertising and must follow all Novartis requirements concerning DTC advertising.
- These include ads appearing in print or electronic media, "800" number scripts and direct mail pieces directed to the lay public. It also includes messages sent via the Internet intended for consumers, although the regulations do not specifically list all the newest media.

The key elements of DTC advertising are that:

a. the message must be prepared in such a way that it is understandable to the average person (see Average Person Readability Standard below), and

b. it must include a "major statement" of benefits and risks, usually more detailed and in simpler language than standard fair balance.

For example, where standard fair balance for Lotensin reads:

"Angioedema and cough have been reported in patients receiving ACE inhibitors. Pregnancy Warning: ACE inhibitors should be discontinued as soon as pregnancy is detected (see Warnings)."

This same message reads as follows in our DTC ad:

"Lotensin should be discontinued as soon as pregnancy is detected because of concerns about its effects on the unborn child. As with other ACE inhibitors, Lotensin has also caused headache, dizziness, and cough, and in rare cases, a potentially dangerous swelling of the mouth and throat. Talk to your doctor about the potential risks and benefits of these medications."